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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 3

Complete If Known

Application Number	10/828,653
Filing Date	April 20, 2004
First Named Inventor	C. Randal Mills et al.
Group Art Unit	3738
Examiner Name	Not Yet Assigned
Attorney Docket Number	15672US01

U.S. PATENT DOCUMENTS

Examiner Initial*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
RY	A1	3,291,640	12/1966	Livingston	
	A2	4,193,818	03/1980	Young et al.	
	A3	4,294,753	10/1981	Urist	
	A4	5,037,437	08/1991	Matsen, III	
	A5	5,066,578	11/1991	Wikman-Coffelt	
	A6	5,213,619	05/1993	Jackson et al.	
	A7	5,288,462	02/1994	Carter et al.	
	A8	5,298,222	03/1994	O'Leary	
	A9	5,333,626	08/02/94	Morse et al.	
	A10	5,380,826	01/1995	Castor et al.	
	A11	5,397,357	03/14/95	Schmieding et al.	
	A12	5,429,810	07/1995	Knaepler et al.	
	A13	5,509,968	04/1996	Carr	
	A14	5,513,662	05/07/96	Morse et al.	
	A15	5,556,379	09/1999	Wolfinbarger et al.	
	A16	5,556,428	09/17/96	Shah	
	A17	5,593,844	11/1999	Abraham et al.	
	A18	5,711,921	01/1998	Langford	
	A19	5,716,454	02/1998	Carr	
	A20	5,725,579	03/1998	Fages et al.	
	A21	5,753,195	5/1998	Langford et al.	
	A22	5,769,893	06/23/98	Shah	
	A23	5,797,871	08/25/98	Wolfinbarger, Jr.	
	A24	5,846,484	12/1998	Scarborough et al.	
	A25	5,976,104	11/02/99	Wolfinbarger, Jr.	
	A26	6,001,106	12/1999	Ryan et al.	
	A27	6,024,735	02/15/00	Wolfinbarger, Jr.	
	A28	6,102,056	08/2000	Kotsopoy	
	A29	6,290,718	09/18/01	Grooms et al.	
	A30	6,293,970	09/25/01	Wolfinbarger, Jr.	
	A31	6,440,444	08/27/02	Boyce et al.	
	A32	6,482,584	11/19/02	Mills et al.	
RY	A33	6,497,726	12/24/02	Carter et al.	

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/Regina Yoo/

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Sheet 2 Of 3

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RY	A34	6,613,278	09/02/03	Mills et al.	
RY	A35	6,652,592	11/25/03	Grooms et al.	
RY	A36	6,652,818	11/05/03	Mills et al.	
RY	A37	6,685,626	02/03/04	Wironen	
RY	A38	6,696,073	02/24/04	Boyce et al.	
RY	A39	6,699,252	03/02/04	Farr, II, et al.	
RY	A40	D461,248	08/06/02	Bianchi et al.	
RY	A41	2001/0031254	10/18/01	Bianchi et al.	
RY	A42	2002/0106393	08/08/02	Bianchi et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² -Number ³ -Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
RY	A43	EP 0424159	10/1990			
RY	A44	JP 03/224570	01/1990			
RY	A45	WO 94/11035	05/1994			
RY	A46	WO 97/27882	07/1997			
RY	A47	WO 98/41245	09/1998			
RY	A48	WO 99/47080	09/1999			

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
RY	A49	Piet, M.P.J., et al., The use of tri(n-butyl) phosphate detergent mixtures to inactivate hepatitis viruses and human immunodeficiency virus in plasma and plasma's subsequent fractionation, Transfusion vol. 30, No.: 7, 1990, pp. 591-598.
RY	A50	Hellstern, et al., Vox Sang, 1992:63:178-185, Manufacture and in vitro Characterization of Solvent/Detergent-Treated Human Plasma.
RY	A51	Horowitz, B. et al., Solvent/Detergent-Treated Plasma: A Virus-Inactivated Substitute for Fresh Frozen Plasma.
RY	A52	Carr, James, et al. "A Feasibility Study for Removing Tissue Contamination from Porous Implants." Biomedical Instrumentation and Technology. May/Jun. 1995. 220-225.
RY	A53	Levine, David, et al. "Cost Awareness and Containment for the 1990's: Recycling Orthopaedic Implants." Contemporary Orthopaedics, Oct. 1992. 25(4): 376-381.
RY	A54	American National Standard. "Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices." Association for the Advancement of Medical Instrumentation, 1991. 1-14.
RY	A55	Brown, John Stuart. "An Ultrasonic Cleaning Bath in General Practice." Practitioner, Apr. 8, 1988. 232: 377.

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Sheet	3	Of	3

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RY	A56	University of Florida Tissue Bank, Inc. "Threaded Cortical Dowel: Processing and Screening Methods." Technical Monograph, 1996. 1-6.
RY	A57	Grafton Demineralized Bone Matrix (DBM) "First Consider the Source: Musculoskeletal Transplant Foundation." Osteotech, Inc., 1995.
RY	A58	Wolfenbarger, et al. "A Comprehensive Study of Physical Parameters, Biomechanical Properties, and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery." Spine, 1994. 19(3): 277-283.
RY	A59	Stanford, C.M. et al. "Bone Cell Expression on Titanium Surfaces is Altered by Sterilization Treatments." J Dent Res, May 1994. 73(5): 1061-1071.
RY	A60	Evanoff, Jean. "Sterilizing and Preserving Human Bone." AORN Journal, Apr. 1983. 37(5): 972-980.
RY	A61	Petri, W.H., et al. "Demineralized Bone Sterilization." J Dent Res, 1993. 72 (IADR Abstracts) 417.
RY	A62	Bloom, D.S., et al. "Effects of Multiple Sterilization in the Monocortical Screw-Bone Interface." J Dent Res, 1996. 75 (IADR Abstracts) 335.
RY	A63	Liu, Yu et al. "Detergent Treatment on Canine Tracheal Allograft." Transplantation, 1999. 67(9): S649.
RY	A64	Voggenreiter, G. et al. "Effects of Preservation and Sterilization on the Biomechanical Properties of Cortical Bone Grafts." J. Biomechanics, 1991. 24(6): 458.
RY	A65	Mschvidobadse, Von M.V. "Allogenic Transplantation of Sterilized Bones and Halfjoints." Zbl. Chirurgie, 1978. 103: 1138-1148.
RY	A66	American Red Cross, "Aseptically-Processes Bone and Connective Tissue." ARC, North Central Region, 1995.
RY	A67	Database WPI, Section PQ, Week 199429, Dewetn Publications, Ltd., London, GB; Class P32, AN 1994-239698, XP002135434 & SU 1 811 817 A (Traumatology Orthopaedy Res Inst.), Apr. 30, 1993 abstract.
RY	A68	Maddox, EWA, et al. "Optimizing Human Demineralized Bone Matrix for Clinical Application" Burgess, 529-534.

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RY	A1	3,318,774	06/22/65	Dingwall et al.	
RY	A2	4,300,243	02/08/80	Baumgartner	
RY	A3	4,553,974	08/14/84	Dewanjee	
RY	A4	4,801,299	02/22/84	Brendel, et al.	
RY	A5	4,871,366	05/23/88	von Recum, et al.	
RY	A6	4,890,457	01/02/87	McNally, et al.	
RY	A7	4,950,296	06/13/89	McIntyre	
RY	A8	4,976,733	01/27/89	Girardot	
RY	A9	4,982,730	12/21/88	Lewis, Jr.	
RY	A10	5,095,925	03/13/89	Elledge, et al.	
RY	A11	5,232,857	11/19/90	Lefevre, et al.	
RY	A12	5,507,810	12/21/92	Prewett, et al.	
RY	A13	5,607,476	02/09/96	Prewett, et al.	
RY	A14	5,723,012	12/21/95	Fages, et al.	
RY	A15	5,820,581	03/21/96	Wolfenbarger, Jr.	
RY	A16	5,977,034	03/20/96	Wolfenbarger, Jr.	
RY	A17	5,977,432	06/09/97	Wolfenbarger, Jr., et al.	
RY	A18	6,235,239	03/14/94	Sharma	
RY	A19	2001/0023372	09/20/01	Chen, et al.	

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RY	A20	EP 0 335 851	10/4/89	Malmros Holding, Inc.		
RY	A21	WO 99/51170	10/14/99	Cross-Cart, Inc.		
RY	A22	WO 99/66967	12/29/99	International Heart Institute		
RY	A23	WO 01/26703	04/19/01	International Heart Institute		
RY	A24	Translation of JP 3-224570	10/3/91	Tiyoda Mfg. Co., Ltd.		X
RY	A25	Translation of USSR 952,189	8/28/82	Kiev Scientific Research		X

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RY	A26	Conrad, et al., The Effects of Freeze-Drying and Rehydration on Cancellous Bone, <i>Clinical Orthopaedics and Related Research</i> , Number 290, pp. 279-284 (1993).
RY	A27	West, et al., Ultrasound Debridement of Trabeculated Bone: Effective and Atraumatic, <i>Plastic and Reconstructive Surgery</i> , pp. 561-566, March, 1994.
RY	A28	Frozen Bone & Soft Tissue Allograft, Instruction Sheet , 1994 California Transplant Services, Inc. (October, 1994)
RY	A29	von Versen, et al., The peracetic acid/low pressure cold sterilization - A new method to sterilize corticocancellous bone and soft tissue, <i>Z exp. Chir. Transplant Künstl.</i> pp. 18-21, Organe 22 (1989)

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

1

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C. Randal Mills

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